

Report on Atypical Antipsychotic Use in the Kentucky Medicaid Program

Presentation to the
Pharmacy and Therapeutics Advisory Committee
November 18, 2004

Rebecca J. Cecil, R.Ph.
Deputy Undersecretary for Health
Cabinet for Health and Family Services

Dispelling Myths

- DMS will deny access to medications to persons with mental illness
- DMS will tell physicians how to practice medicine
- DMS will balance the budget on the backs of persons with mental illness
- DMS is more concerned with the cost than quality
- DMS is eliminating waivers

Kentucky Facts

- Kentucky is 4th in the Nation for Obesity
- Diabetes Costs Kentucky Medicaid \$673 Million in SFY 2004
- Asthma Costs Kentucky Medicaid \$435 Million
- Ranking for Behavioral Health?

Purpose

- Goals for New Prior Authorization Criteria
- Review Previous Pharmacy and Therapeutics Advisory Committee Decisions
- Review the Utilization Patterns for Atypical Antipsychotic Medications
- Establish New Prior Authorization Criteria for Atypical Antipsychotics

Goals–Quality

- Quality Medical Care for Adults and Children
- “QUALITY CARE IS LESS EXPENSIVE THAN POOR CARE” (Dr. James W. Holsinger, Jr.)
- Reduce Sentinel Events Associated with Prescribing Atypical Antipsychotics

Black Box Warning

March 1, 2004

Re: Safety data on Zyprexa ® (olanzapine) – Hyperglycemia and Diabetes

Dear Doctor,

Eli Lilly and Company would like to inform you of important labeling changes regarding Zyprexa (olanzapine). The Food and Drug Administration (FDA) has asked all manufacturers of atypical antipsychotic medications, including Lilly, to add a Warning statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including Zyprexa. In addition to Zyprexa, the atypical antipsychotic class includes Clozaril ® (clozapine, Novartis), Risperdal ® (risperidone, Janssen), Seroquel ® (quetiapine, AstraZeneca), Geodon ® (ziprasidone, Pfizer), and Abilify ® (aripiprazole, Bristol Myers Squibb and Otsuka American Pharmaceutical). Accordingly, the Zyprexa prescribing information has been updated with the following information:

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Quality Concern: Adverse Effects

- Atypical Antipsychotics Have Unique Side Effect Profile. Most Significant:
 - Risk of Death or Stroke in Elderly
 - Cardiovascular disturbances
 - Significant weight gain
 - Metabolic disturbances
 - Recent Concern for Pediatric Patients
 - **Sept 2003 FDA requested all 6 agents include warning they can increase risk of hyperglycemia and diabetes.**

Warnings for Pediatric Use

- “Pediatric Patients Have a Greater Risk of Insulin Resistance, Hypertension, Elevated Cholesterol and Triglycerides, and Increased Levels of Protein in the Urine” (2004, Mark A. Riddle, M.D., Johns Hopkins University)
- Pediatric Use must be Weighed Against Side Effects—Safety Profile May not Justify Use for All Patients

Atypical Use and Diabetes:

- About 26,000 Members Use Atypical Antipsychotics Per Month
- 9,433 of the 26,000 Members using Atypical Antipsychotics have a Diabetes Diagnosis (36% of Utilizers)

Previous P&T Decisions

- Effective November 14, 2002, Required a Prior Authorization for Olanzapine (Zyprexa)—
 - (Seroquel, Risperdal, Geodon, and Clozaril did not require PA)
 - Report in November 2003 concluded that the Zyprexa PA had little impact on access and utilization due to extensive grandfathering provision
 - The report also noted concerns for atypical antipsychotic utilization in three areas: off label use, duplicate therapy, and maximum dosages.

Previous P&T Decisions

- March 18 2004:
 - Recommended Risperdal, Seroquel, Clozaril, and Geodon as PDL products
 - Require FDA approved diagnosis on prescription or through PA form
 - Limit maximum dosing to FDA approved levels
 - Limit therapy to a single atypical antipsychotic product (except for 30-day period of crossover during product switching)
 - September 2004--HOLDING IMPLEMENTATION PENDING DETAILED STUDY OF UTILIZATION

Review of Utilization Patterns:

- **There few published studies that evaluate the use of anti-psychotic agents in children.**
- Mark Riddle, 2004
 - Significant Use by Children Needs Close Examination: New Evidence Suggest:
 - Antipsychotic Drugs are Linked to Insulin Resistance in Children
 - Appears to be a dose relationship—use lowest dose possible
 - Weigh relative risks benefits—diabetes and heart disease vs. other treatment options for behavioral health problems.
- Robert Findling 2003-use lowest effective dose
- Lesley Curtis 2004—pediatric use of atypicals is growing with little evidence of efficacy—side effects impact pediatric patients more than adults.
- Martin A, L'Ecuyer S. Triglyceride, cholesterol and weight changes among risperidone-treated youths. A retrospective study. *Eur Child Adolesc Psychiatry*. 2002 Jun;11(3):129-33.
- Alfaro CL, Wudarsky M, Nicolson R, et al. Correlation of antipsychotic and prolactin concentrations in children and adolescents acutely treated with haloperidol, clozapine, or olanzapine. *J Child Adolesc Psychopharmacol*. 2002 Summer;12(2):83-91.
- Patel NC, Sanchez RJ, Johnsrud MT, Crismon ML. Trends in antipsychotic use in a Texas medicaid population of children and adolescents: 1996 to 2000. *J Child Adolesc Psychopharmacol*. 2002 Fall;12(3):221-9.

Review of Utilization Patterns:

Age Distribution of Atypical Antipsychotic Utilization Kentucky Medicaid									
August 2004									
Age Group	ABILIFY	CLOZAPINE	GEODON	RISPERDAL	RISPERDAL CONSTA	SEROQUEL	ZYPREXA	ZYPREXA ZYDIS	NUMBER OF MBRS
0 - 18	44.99%	3.09%	22.11%	36.06%	1.25%	25.26%	6.69%	16.81%	6,296
19 - 30	10.95%	13.40%	16.18%	7.10%	23.75%	10.12%	8.08%	13.79%	2,159
31 - 50	27.87%	65.98%	39.70%	20.91%	42.50%	34.94%	31.26%	29.31%	6,898
51 - 65	9.96%	15.46%	13.45%	12.73%	26.25%	13.97%	23.58%	16.81%	3,609
Over 65	6.23%	2.06%	8.56%	23.20%	6.25%	15.70%	30.40%	23.28%	4,789
Totals	1,927	97	1,063	8,286	80	7,299	4,767	232	23,751

**No Products are Approved for Pediatric Use

**Risperdal is the only product with RCT Studies for Pediatric Use

Are Medicaid Patients Prescribed Dosages Above FDA Recommended Levels?

- Detail Dosing Distribution by each product
- Highlight Members Exceeding FDA Recommended Levels
- Fiscal Year 2004

FDA LABEL EXCERPTS

Antipsychotic agent	Target dose	Higher dose	Titration frequency
Abilify	10 to 15 mg once daily	10 to 30 mg once a day- similar efficacy	Titrate after 2 weeks
Clozaril	300 to 600 mg/day	600 to 900 mg ; Do not exceed 900mg	Titrate based on efficacy and tolerability
Geodon	20 mg twice a day	20 to 100 mg twice a day; Do not exceed 80 mg twice a day	Not less than 2 days
Risperdal	4 mg to 16 mg/day	6 mg BID- similar efficacy; doses above 16 mg not studied	Not less than 1 week
Seroquel	150 mg to 800 mg/day	300 mg similar efficacy; doses above 800 mg/day safety not studied	Not less than 2 days
Zyprexa	10 mg to 15 mg once daily	Doses above 10 mg similar efficacy; doses above 20 mg not studied	Not less than 1 week

Atypical Antipsychotic Utilization Maximum Dosage Information

Kentucky Medicaid
SFY 2004

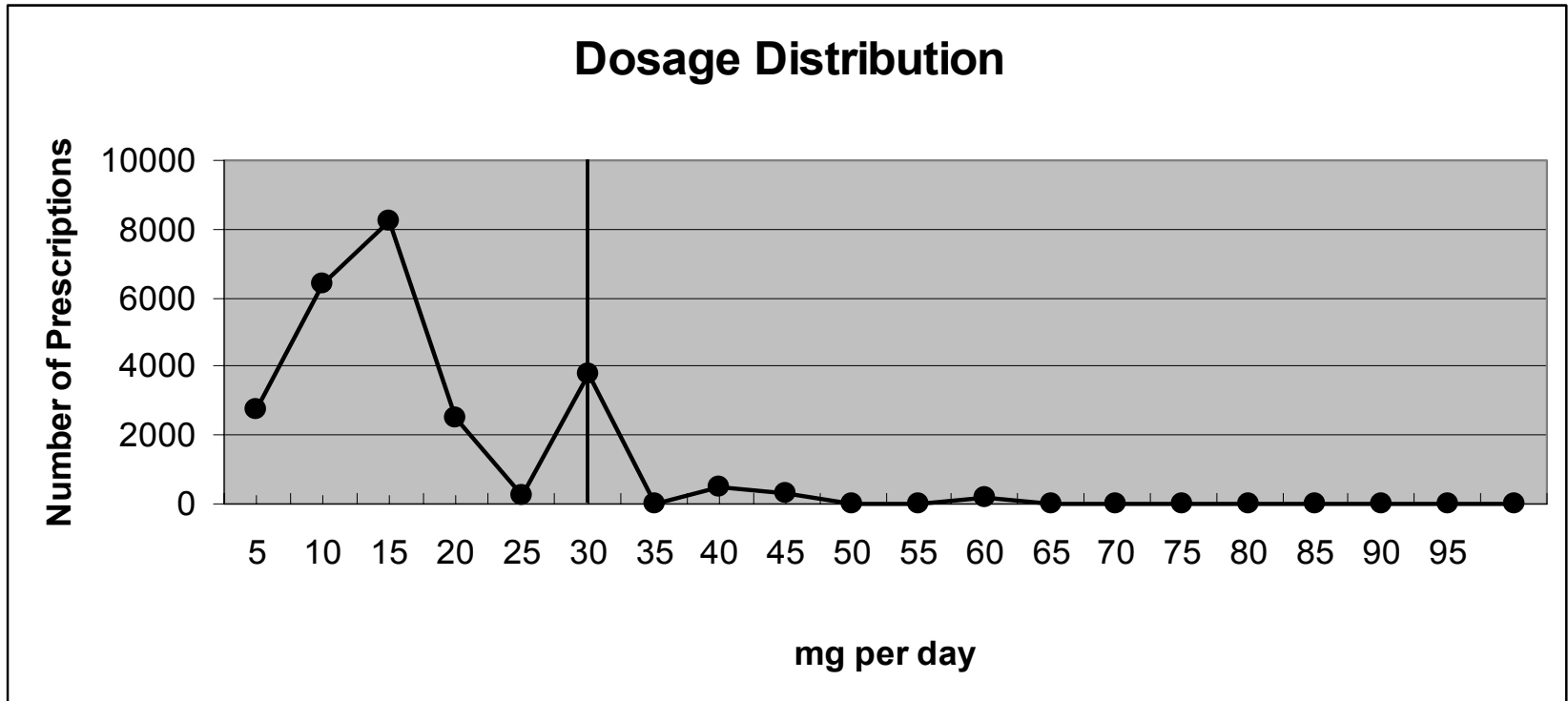
Drug Name	FDA Maximum Dosage	Number of Members Above Maximum Dosage	Percent of Members Using Product
Abilify	30 MG	234	4.2%
Clozapine	900 MG	13	2.8%
Geodon	160 MG	351	10.4%
Risperdal	16 MG	37	0.2%
Seroquel	800 MG	556	3.1%
Zyprexa	20 MG	1,619	13.1%
TOTAL		2,810	

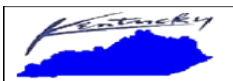


Atypical Antipsychotic Usage In Excess of Maximum Recommended Daily Dosage

Brand Name: Abilify
Maximum Recommended Dosage: 30 MG
Time Period: 7/1/2003 - 6/30/2004

	<u>Count</u>	<u>Percentage</u>
Patients With One or More Prescription in Excess of Recommended Dosage:	234	4.23%
Patients Where All Prescriptions Are Within Guideline:	5295	95.77%
Total Patients Receiving Medication:	5529	100.00%
	<u>Cost Totals</u>	<u>Percentage</u>
Prescriptions in Excess of Recommended Dosage:	\$815,172.12	9.65%
Prescriptions Within Guideline:	\$7,636,531.13	90.35%
All Prescriptions For This Medication:	\$8,451,703.25	100.00%

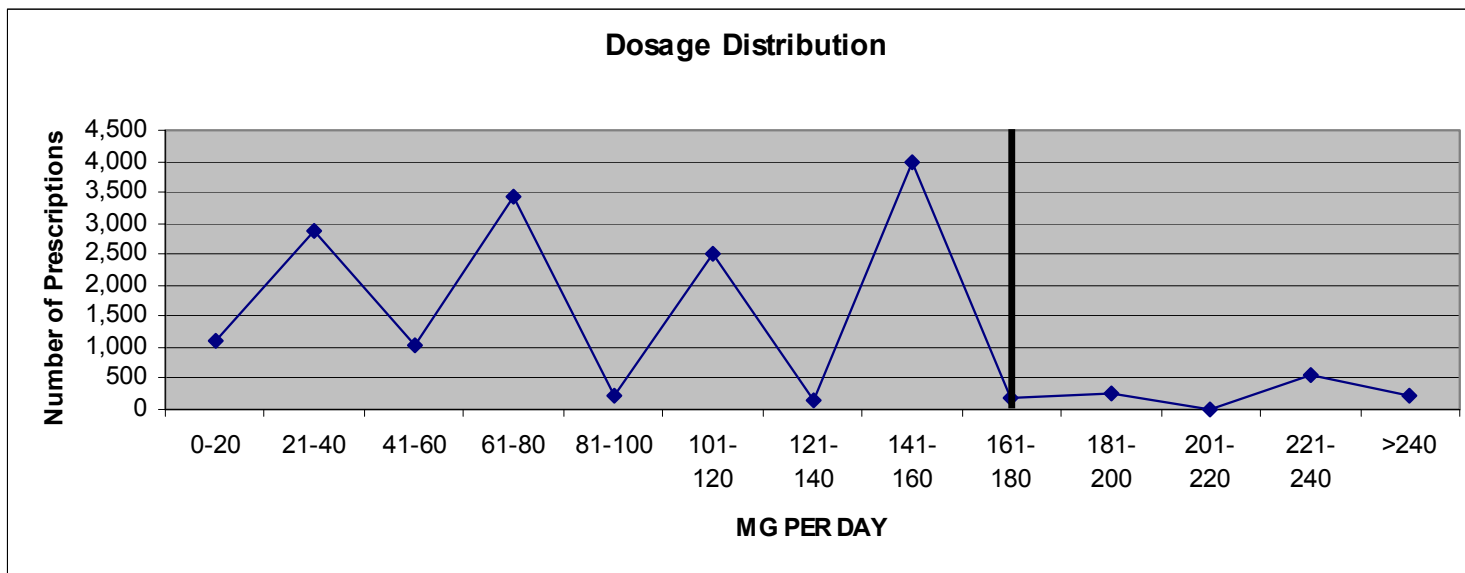


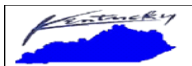


Atypical Antipsychotic Usage In Excess of Maximum Recommended Daily Dosage

Brand Name: Geodon
Maximum Recommended Dosage: 160 MG
Time Period: 7/1/2003 - 6/30/2004

	<u>Count</u>	<u>Percentage</u>
Patients With One or More Prescription in Excess of Recommended Dosage:	351	10.41%
Patients Where All Prescriptions Are Within Guideline:	3022	89.59%
Total Patients Receiving Medication:	3373	100.00%
	<u>Cost Totals</u>	<u>Percentage</u>
Prescriptions in Excess of Recommended Dosage:	\$503,569.89	12.21%
Prescriptions Within Guideline:	\$3,619,363.65	87.79%
All Prescriptions For This Medication:	\$4,122,933.54	100.00%

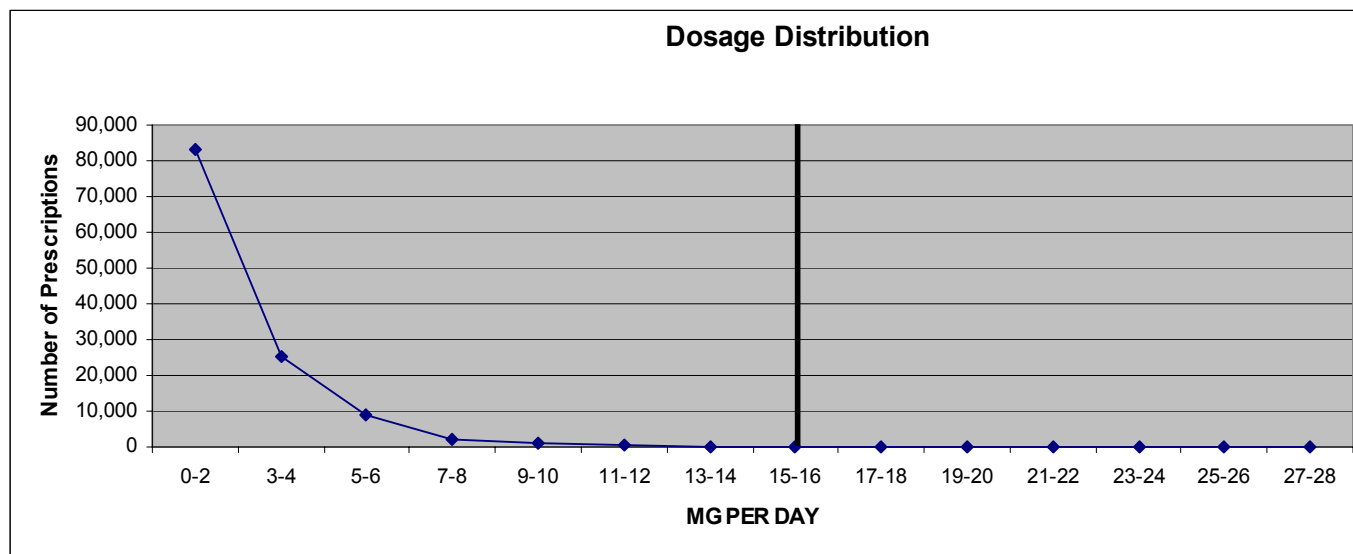


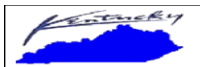


Atypical Antipsychotic Usage In Excess of Maximum Recommended Daily Dosage

Brand Name: Risperdal
Maximum Recommended Dosage: 16 MG
Time Period: 7/1/2003 - 6/30/2004

	<u>Count</u>	<u>Percentage</u>
Patients With One or More Prescription in Excess of Recommended Dosage:	37	0.19%
Patients Where All Prescriptions Are Within Guideline:	19687	99.81%
Total Patients Receiving Medication:	19724	100.00%
	<u>Cost Totals</u>	<u>Percentage</u>
Prescriptions in Excess of Recommended Dosage:	\$55,446.45	0.25%
Prescriptions Within Guideline:	\$22,077,367.41	99.75%
All Prescriptions For This Medication:	\$22,132,813.86	100.00%

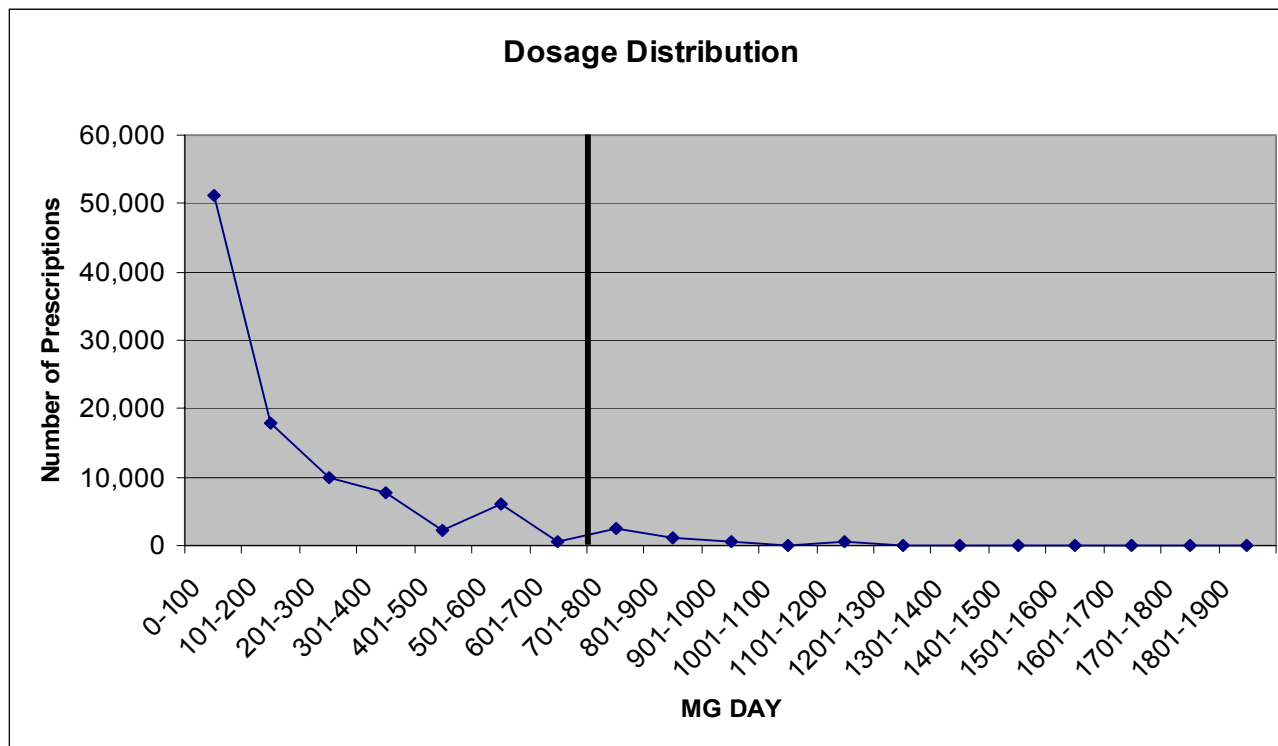




Atypical Antipsychotic Usage In Excess of Maximum Recommended Daily Dosage

Brand Name: Seroquel
Maximum Recommended Dosage: 800 MG
Time Period: 7/1/2003 - 6/30/2004

	<u>Count</u>	<u>Percentage</u>
Patients With One or More Prescription in Excess of Recommended Dosage:	556	3.11%
Patients Where All Prescriptions Are Within Guideline:	17319	96.89%
Total Patients Receiving Medication:	17875	100.00%
	<u>Cost Totals</u>	<u>Percentage</u>
Prescriptions in Excess of Recommended Dosage:	\$1,717,567.69	9.11%
Prescriptions Within Guideline:	\$17,145,789.35	90.89%
All Prescriptions For This Medication:	\$18,863,357.04	100.00%

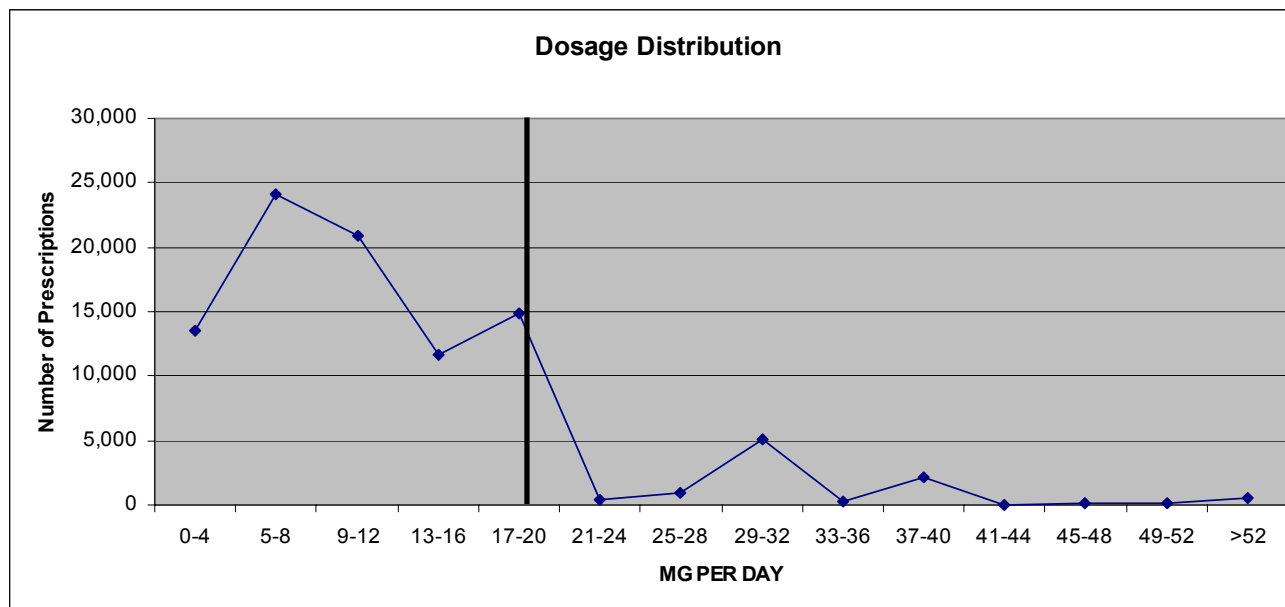




Atypical Antipsychotic Usage In Excess of Maximum Recommended Daily Dosage

Brand Name: Zyprexa
Maximum Recommended Dosage: 20 MG
Time Period: 7/1/2003 - 6/30/2004

	<u>Count</u>	<u>Percentage</u>
Patients With One or More Prescription in Excess of Recommended Dosage:	1619	13.12%
Patients Where All Prescriptions Are Within Guideline:	10717	86.88%
Total Patients Receiving Medication:	12336	100.00%
	<u>Cost Totals</u>	<u>Percentage</u>
Prescriptions in Excess of Recommended Dosage:	\$8,222,742.13	25.17%
Prescriptions Within Guideline:	\$24,447,802.98	74.83%
All Prescriptions For This Medication:	\$32,670,545.11	100.00%



Duplicate Therapy/Polypharmacy

- Report Overall Utilization Profiles
- Selected a case study of duplicate therapy
- Reports a single month of all prescription information



Kentucky State Hospitals Antipsychotic Utilization Profile October 2003

<u>Type of Therapy</u>	<u>Number of Patien</u>	<u>Percent of Total</u>	<u>Number of Patients</u>
Abilify Only	49	0.36%	
Clozapine Only	29	0.21%	
Geodon Only	115	0.84%	
Risperdal Only	2,207	16.20%	
Seroquel Only	1,183	8.69%	
Zyprexa Only	2,071	15.20%	
TA Only	921	6.76%	
			<u>Monotherapy Subtotals:</u>
1 AA + Clozapine	79	0.58%	<u>6,575</u>
1 AA + TA	2,734	20.07%	
Clozapine + TA	211	1.55%	
2 AA	1,321	9.70%	
2 AA + TA	1,526	11.20%	
2 AA + Clozapine	69	0.51%	
3 AA	223	1.64%	
3 AA + TA	592	4.35%	
3 AA + Clozapine	58	0.43%	
4 AA	29	0.21%	
4 AA + TA	137	1.01%	
4 AA + Clozapine	27	0.20%	
5 AA	1	0.01%	
5 AA + TA	27	0.20%	
5 AA + Clozapine	12	0.09%	
			<u>Polytherapy Subtotals:</u>
Totals for All Types of Therapy:	13,621	100%	13,621

Number of Patients

Number on any Atypical (including Clozapine)	12,310
Number on any Antipsychotic	13,231

TA = Typical Antipsychotic (Chlorpromazine, Haloperidol, Trifluoperazine)
AA = Atypical Antipsychotic - excluding Clozapine

Duplicate Therapy/Polypharmacy

Antipsychotic Utilization Profile

Kentucky Medicaid Program

AUGUST 2004

Categories are Mutully Exclusive

MONOTHERAPY GROUP	Number of Patients	DUPLICATE THERAPY GROUP	Number of Patients
ABILIFY	1,927	Clozaril + AA	91
CLOZARIL	99	AA + TA	618
GEODON	1,063	2 AA	1,875
RISPERDAL	8,366	2 AA + TA	80
SEROQUEL	7,299	2 AA + CL	10
ZYPREXA	4,999	3 AA	68
TA	1,095	3 AA + TA	3
Total Monotherapy	24,848	4 AA	4
		5 AA	1
		Total Duplicate Therapy	2,750

All Use is for full 30 day supply of each product during the month

AA = Atypical Antipsychotic

TA = Typical Antipsychotic (CHLORPROMAZINE,
HALOPERIDOL, TRIFLUOPERAZINE)

Duplicate Therapy/Polypharmacy: Case Example



Kentucky Department for Medicaid Services



27 YEAR OLD FEMALE
OUTPATIENT

*****Has no psychiatric visits in her history-- all meds from Internist**

Fill Date	Brand Name	Drug Category	Strength	Quantity	Days Supplied
2/6/2004	ACETAMINOPHEN/BUTALBITAL/CAFFEINE	ANALGESIC COMBINATIONS	500 MG-50 MG-40 MG	60	8
2/6/2004	LORAZEPAM	BENZODIAZEPINES	1 MG	60	30
2/6/2004	METOPROLOL TARTRATE	CARDIOSELECTIVE BETA BLOCKERS	50 MG	30	30
2/6/2004	CEPHALEXIN MONOHYDRATE	FIRST GENERATION CEPHALOSPORINS	MONOHYDRATE 500 MG	21	7
2/6/2004	LAMICTAL	MISCELLANEOUS ANTICONVULSANTS	100 MG	60	30
2/6/2004	TRAZODONE HYDROCHLORIDE	MISCELLANEOUS ANTIDEPRESSANTS	150 MG	120	30
2/6/2004	NEFAZODONE	MISCELLANEOUS ANTIDEPRESSANTS	200 MG	90	30
2/6/2004	ZYPREXA	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	10 MG	60	30
2/6/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	200 MG	90	30
2/6/2004	TIZANIDINE	SKELETAL MUSCLE RELAXANTS	4 MG	60	30
2/6/2004	LEXAPRO	SSRI ANTIDEPRESSANTS	10 MG	15	30
2/8/2004	ADVAIR DISKUS	BRONCHODILATOR COMBINATIONS	250 MCG-50 MCG	60	30
2/8/2004	LUPRON DEPOT-GYN	HORMONES/ANTINEOPLASTICS	11.25 MG	1	30
2/19/2004	ABILIFY	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	10 MG	45	30
2/20/2004	ACETAMINOPHEN/BUTALBITAL/CAFFEINE	ANALGESIC COMBINATIONS	500 MG-50 MG-40 MG	60	8
2/20/2004	ZYPREXA ZYDIS	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	20 MG	30	30
2/20/2004	OXAPROZIN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	600 MG	30	15
2/27/2004	LUPRON DEPOT-GYN	HORMONES/ANTINEOPLASTICS	11.25 MG	1	30

Date	Diagnosis Code	Diagnosis
4/28/2004	845.00	SPRAIN OF ANKLE NOS
4/15/2004	617.3	PELV PERIT ENDOMETRIOSIS
4/6/2004	719.47	JOINT PAIN-ANKLE
4/6/2004	729.5	PAIN IN LIMB
3/18/2004	845.00	SPRAIN OF ANKLE NOS
3/18/2004	845.10	SPRAIN OF FOOT NOS
3/13/2004	719.47	JOINT PAIN-ANKLE
2/25/2004	789.03	ABDMNAL PAIN RT LWR QUAD
1/30/2004	617.9	ENDOMETRIOSIS NOS
1/30/2004	789.07	ABDMNAL PAIN GENERALIZED
1/2/2004	625.9	FEM GENITAL SYMPTOMS NOS
1/2/2004	716.90	ARTHROPATHY NOS-UNSPEC

Duplicate Therapy/Polypharmacy: Case Example



Kentucky Department for Medicaid Services



11 Year Old female

OUTPATIENT

***Has no psychiatric visits in history-all meds from Internist

Fill Date	Brand Name	Drug Category	Strength	Quantity	Days Supply
6/16/2004	CONCERTA	CNS STIMULANTS	54 MG/24 HR	30	30
6/7/2004	PAXIL CR	SSRI ANTIDEPRESSANTS	12.5 MG	30	30
6/7/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	25 MG	90	30
6/7/2004	TRAZODONE HYDROCHLORIDE	MISCELLANEOUS ANTIDEPRESSANTS	50 MG	30	30
6/7/2004	SINGULAIR	LEUKOTRIENE MODIFIERS	5 MG	30	30
6/7/2004	METOCLOPRAMIDE HYDROCHLORIDE	GI STIMULANTS	5 MG	120	30
6/7/2004	LORATADINE	ANTIHISTAMINES	10 MG	30	30
6/7/2004	CLONIDINE	ANTIADRENERGIC AGENTS, CENTRALLY AC	0.1 MG	30	30
6/7/2004	PROVENTIL HFA	ADRENERGIC BRONCHODILATORS	108 MCG/INH	7	10
6/1/2004	PAXIL CR	SSRI ANTIDEPRESSANTS	12.5 MG	30	30
6/1/2004	ZYPREXA	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	10 MG	30	30
6/1/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	25 MG	90	30
6/1/2004	TRAZODONE HYDROCHLORIDE	MISCELLANEOUS ANTIDEPRESSANTS	50 MG	30	30
6/1/2004	SINGULAIR	LEUKOTRIENE MODIFIERS	5 MG	30	30
6/1/2004	PROVENTIL HFA	ADRENERGIC BRONCHODILATORS	108 MCG/INH	7	10

Date	Diagnosis Code	Diagnosis
6/30/2004	300.02	GENERALIZED ANXIETY DIS
6/30/2004	314.01	ATTN DEFICIT W HYPERACT
3/18/2004	367.0	HYPERMETROPIA
3/18/2004	367.21	REGULAR ASTIGMATISM
3/18/2004	372.14	CHR ALLRG CONJUNCTIV NEC
3/12/2004	034.0	STREP SORE THROAT
12/30/2003	382.9	OTITIS MEDIA NOS
12/16/2003	382.00	AC SUPP OTITIS MEDIA NOS
12/16/2003	388.60	OTORRHEA NOS
6/24/2003	079.99	VIRAL INFECTION NOS
3/20/2003	530.81	ESOPHAGEAL REFLUX
3/3/2003	787.03	VOMITING ALONE
1/2/2003	780.6	FEVER

Duplicate Therapy/Polypharmacy: Case Example



Kentucky Department for Medicaid Services



10 Year Old female

OUTPATIENT

***Psychiatric provider

Fill Date	Brand Name	Drug Category	Strength	Quantity	Days Supply
6/29/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	300 MG	30	30
6/29/2004	TOPAMAX	MISCELLANEOUS ANTICONVULSANTS	200 MG	30	30
6/15/2004	FLUOXETINE HYDROCHLORIDE	SSRI ANTIDEPRESSANTS	20 MG	30	30
6/10/2004	NEURONTIN	MISCELLANEOUS ANTICONVULSANTS	400 MG	90	30
6/8/2004	NEURONTIN	MISCELLANEOUS ANTICONVULSANTS	100 MG	90	30
6/4/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	200 MG	90	30
6/4/2004	RISPERDAL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	0.25 MG	60	30
6/4/2004	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	25 MG	120	30

Date	Diagnosis Code	Diagnosis
6/30/2004	299.80	CHILD PSYCHOS NEC-ACTIVE
6/1/2004	348.9	BRAIN CONDITION NOS
6/1/2004	788.30	URINARY INCONTINENCE NOS
5/28/2004	465.9	ACUTE URI NOS
5/28/2004	786.2	COUGH
4/5/2004	616.10	VAGINITIS NOS
4/5/2004	780.39	CONVULSIONS NEC
1/14/2004	780.39	CONVULSIONS NEC
1/13/2004	V58.69	LONG-TERM USE MEDS NEC
12/30/2003	079.99	VIRAL INFECTION NOS
6/7/2003	367.1	MYOPIA
6/2/2003	315.9	DEVELOPMENT DELAY NOS
6/2/2003	367.1	MYOPIA
5/27/2003	312.00	UNSOCIAL AGGRESS-UNSPEC
5/27/2003	348.0	CEREBRAL CYSTS
5/27/2003	348.8	BRAIN CONDITIONS NEC
5/20/2003	V64.3	NO PROC FOR REASONS NEC
5/7/2003	299.00	INFANTILE AUTISM-ACTIVE

Duplicate Therapy/Polypharmacy: Case Example



Kentucky Department for Medicaid
Services



69 Year Old Male

LTC PATIENT

TOTAL RX COSTS = \$1,714.50 for MONTH PERIOD ENDING 12/31/2003

*****Has no psychiatric visits in history-all meds from Internist**

Fill Date	Brand Name	Drug Category	Strength	Quantity	Days
12/31/2003	LORAZEPAM	BENZODIAZEPINES	1 MG	7	7
12/30/2003	SUCRALFATE	MISCELLANEOUS GI AGENTS	1 GM	112	28
12/26/2003	RISPERDAL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	0.25 MG	84	28
12/24/2003	LORAZEPAM	BENZODIAZEPINES	1 MG	7	7
12/17/2003	LORAZEPAM	BENZODIAZEPINES	1 MG	7	7
12/16/2003	PAROXETINE HYDROCHLORIDE	SSRI ANTIDEPRESSANTS	20 MG	28	28
12/15/2003	ZYPREXA ZYDIS	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	5 MG	30	30
12/15/2003	ZYPREXA ZYDIS	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	20 MG	28	28
12/10/2003	ABILIFY	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	15 MG	28	28
12/10/2003	LORAZEPAM	BENZODIAZEPINES	1 MG	7	7
12/3/2003	GEODON	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	20 MG	56	28
12/3/2003	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	25 MG	56	28
12/3/2003	LORAZEPAM	BENZODIAZEPINES	1 MG	7	7
12/1/2003	SUCRALFATE	MISCELLANEOUS GI AGENTS	1 GM	112	28

Date	Diagnosis Code	Diagnosis
5/1/2004	V15.4	PSYCHOLOGICAL TRAUMA-NEGLECT
4/16/2004	496	CHR AIRWAY OBSTRUCT NEC
11/5/2003	440.2	ATHSCL EXTRM NTV ART NOS
11/5/2003	703.8	DISEASES OF NAIL NEC
11/5/2003	729.5	PAIN IN LIMB
8/4/2003	600	HYPERTROPHY OF PROSTATE
8/4/2003	V76.41	SCREEN MAL NEOP-RECTUM

Duplicate Therapy/Polypharmacy: Case Example



Kentucky Department for Medicaid Services



47 YEAR OLD MALE

OUTPATIENT

TOTAL RX COSTS 12 MONTH PERIOD ENDING 3/31/2004 - \$30,324.22

FILL_DT	BRAND	CATEGORY	QTY	STRENGTH	DAYS Supply
5/5/2003	TRILEPTAL	MISCELLANEOUS ANTICONVULSANTS	60	300 MG	30
5/5/2003	NEURONTIN	MISCELLANEOUS ANTICONVULSANTS	60	300 MG	30
5/5/2003	TOPAMAX	MISCELLANEOUS ANTICONVULSANTS	240	100 MG	30
5/5/2003	ZYPREXA	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	30	20 MG	30
5/5/2003	SEROQUEL	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	60	200 MG	30
5/5/2003	GEODON	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	60	40 MG	30
5/5/2003	BUSPIRONE HYDROCHLORIDE	MISCELLANEOUS ANXIOLYTICS, SEDATIVES AND HYPNOTICS	60	30 MG	30
5/5/2003	FLUOXETINE HYDROCHLORIDE	SSRI ANTIDEPRESSANTS	90	20 MG	30
5/27/2003	TOPAMAX	MISCELLANEOUS ANTICONVULSANTS	240	100 MG	30
5/27/2003	ZYPREXA	MISCELLANEOUS ANTIPSYCHOTIC AGENTS	30	20 MG	30
5/27/2003	BUSPIRONE HYDROCHLORIDE	MISCELLANEOUS ANXIOLYTICS, SEDATIVES AND HYPNOTICS	60	30 MG	30

DATE	DIAGNOSIS CODE	DIAGNOSIS	
6/29/2004	296.32	RECURR DEPR PSYCHOS-MOD	

Requiring Diagnosis for Use

- 2003 P&T Study reported about 50% of Medicaid members using atypical antipsychotics did not have an FDA approved ICD-9 diagnosis during the previous year (from professional or institutional claims)
- Medicaid began collecting diagnosis information from prescriptions in September 2004
- Prescription diagnosis information reveals differences between prescription/professional claims

**Diagnosis Codes from Atypical Antipsychotic Prescriptions
Kentucky Medicaid Program, Fee-for-service
September 2004 (Includes 21,246 prescriptions)**

Currently in Approved Category on Unisys PA indicator

Diagnosis	Description	# Members	Percent	Cumulative
296	AFFECTIVE PSYCHOSES	10012	47.1%	47.1%
295	SCHIZOPHRENIC DISORDERS	7266	34.2%	81.3%
299	PSYCHOSES OF CHILDHOOD	1418	6.7%	88.0%
301	SCHIZOID PERSONALITY NOS	712	3.3%	91.3%
290	SENILE DEMENTIA	444	2.1%	93.4%
294	OTHER ORGANIC PSYCH COND	349	1.6%	95.0%

Other, Non-approved Categories

298	OTH NONORGANIC PSYCHOSES	232	1.1%	96.1%
314	HYPERKINETIC SYNDROME	94	0.4%	96.6%
300	NEUROTIC DISORDERS	64	0.3%	96.9%
250	DIABETES MELLITUS	51	0.2%	97.1%
297	PARANOID STATES	45	0.2%	97.3%
312	CONDUCT DISTURBANCE NEC	44	0.2%	97.5%
311	DEPRESSIVE DISORDER NEC	43	0.2%	97.7%
310	NONPSYCHOT BRAIN SYN NOS	41	0.2%	97.9%
309	ADJUSTMENT REACTION	38	0.2%	98.1%
307	TICS	37	0.2%	98.3%
313	EMOTIONAL DIS CHILD/ADOL	35	0.2%	98.4%
401	ESSENTIAL HYPERTENSION	30	0.1%	98.6%
331	CEREBRAL DEGENERATION	29	0.1%	98.7%
291	ALCOHOL WITHDRAWAL	29	0.1%	98.9%
780	HALLUCINATIONS	23	0.1%	99.0%
293	TRANSIENT ORG MENTAL DIS	22	0.1%	99.1%
224	BENIGN NEOPLASM OF EYE	11	0.1%	99.1%
269	OTH NUTRITION DEFICIENCY	10	0.0%	99.2%
259	OTH ENDOCRINE DISORDERS	8	0.0%	99.2%

Rx Diagnosis Verification for Atypical Antipsychotics

Kentucky Medicaid Program

September - October 2004 Rx Claims

- Comparing RX Based Diagnoses with Medical Claims Based Diagnoses:
 - 67% of Members Have Matching RX and Medical Diagnoses
 - 33% of Members Have APPROVED RX Diagnosis WITHOUT Approved Medical Diagnosis

FRADULENT ACTS AND PENALTIES (205.8463)

1) No person shall knowingly or wantonly devise a scheme or plan a scheme or artifice, or enter into an agreement, combination, or conspiracy to obtain or aid another in obtaining payments from any medical assistance program under this chapter by means of any fictitious, false, or fraudulent application, claim, report, or document submitted to the Cabinet for Health Services, or intentionally engage in conduct which advances the scheme or artifice.

(2) **No person shall intentionally, knowingly, or wantonly make, present, or cause to be made or presented to an employee or officer of the Cabinet for Health Services any false, fictitious, or fraudulent statement, representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment.**

(3) No person shall, with intent to defraud, knowingly make, or induce, or seek to induce the making of a false statement or false representation of a material fact with respect to the conditions or operations of an institution or facility in order that the institution or facility may qualify, upon initial certification or upon recertification, as a hospital, skilled-nursing facility, intermediate-care facility, home-health agency, or other provider of services to the Medical Assistance Program.

(4) No person shall, in any matter within the jurisdiction of the Cabinet for Health Services under this chapter, knowingly falsify, conceal, or cover up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry.

(5) **Any person who violates subsections (1) and (2) of this section shall be guilty of a Class A misdemeanor unless the sum total of benefits or payments claimed in any application, claim, report, or document, or in any combination or aggregation thereof, is valued at three hundred dollars (\$300) or more in which case it shall be a Class D felony.** Any person who violates the provisions of subsection (3) of this section shall be guilty of a Class C felony. Any person who violates the provisions of subsection (4) of this section shall be guilty of a Class D felony.

Effective: July 15, 1998

History: Amended 1998 Ky. Acts ch. 426, sec. 226, effective July 15, 1998. -- Created 1994 Ky. Acts ch. 96, sec. 7, effective July 15, 1994; and ch. 316, sec. 7, effective July 15, 1994.

Requiring Diagnosis for Use

- Differences Between Psychiatrists and Non-psychiatrists Prescribers:
 - A study of Zyprexa Prescribing in Kentucky Medicaid from 1998-2003 found:
 - psychiatrists prescribed Zyprexa for off-label purposes in less than 32% of the cases
 - non psychiatrists prescribed Zyprexa for off-label purposes in more than 58% of the cases, and by 2003, the rate had increased to 70.8%



Approved Therapy Compliance For Antipsychotic Medications Kentucky Medicaid Program October 2003

Patients 18 Years of Age or Older

Polypharmacy	Yes	Yes	Yes	Yes	No	No	No	No	Total Patients in Age Group Receiving Atypical Antipsychotic Medications
Exceeds FDA Max Dose	Yes	Yes	No	No	Yes	Yes	No	No	
Off Label	Yes	No	No	Yes	Yes	No	Yes	No	
Number of Patients	28	247	1,274	152	85	681	4,192	12,587	19,246
Percent of Patients	0.15%	1.28%	6.62%	0.79%	0.44%	3.54%	21.78%	65.40%	100.00%

Patients Under 18 Years of Age

Polypharmacy	Yes	Yes	Yes	Yes	No	No	No	No	Total Patients in Age Group Receiving Atypical Antipsychotic Medications
Exceeds FDA Max Dose	Yes	Yes	No	No	Yes	Yes	No	No	
Off Label	Yes	No	No	Yes	Yes	No	Yes	No	
Number of Patients	3	12	182	54	5	39	2,271	3,099	5,665
Percent of Patients	0.05%	0.21%	3.21%	0.79%	0.09%	0.69%	40.09%	54.70%	100.00%

Review of Utilization Patterns: Member data

- Pharmacy Budget is about \$750 Million for SFY 2004
 - Atypical Antipsychotic Expense is \$85 Million for SFY 2004 (11.3%)
- Typically about 680,000 Medicaid Members Eligible Each Month
 - About 26,000 Use Atypical Antipsychotics each month (3.8% of eligible members)
- Based on the Top 10 Drugs, Members taking Atypical Antipsychotics (4%) Account for 41% of Total Dollars

Review of Utilization Patterns:

Top 10 Drugs in Medicaid (SFY 2004)

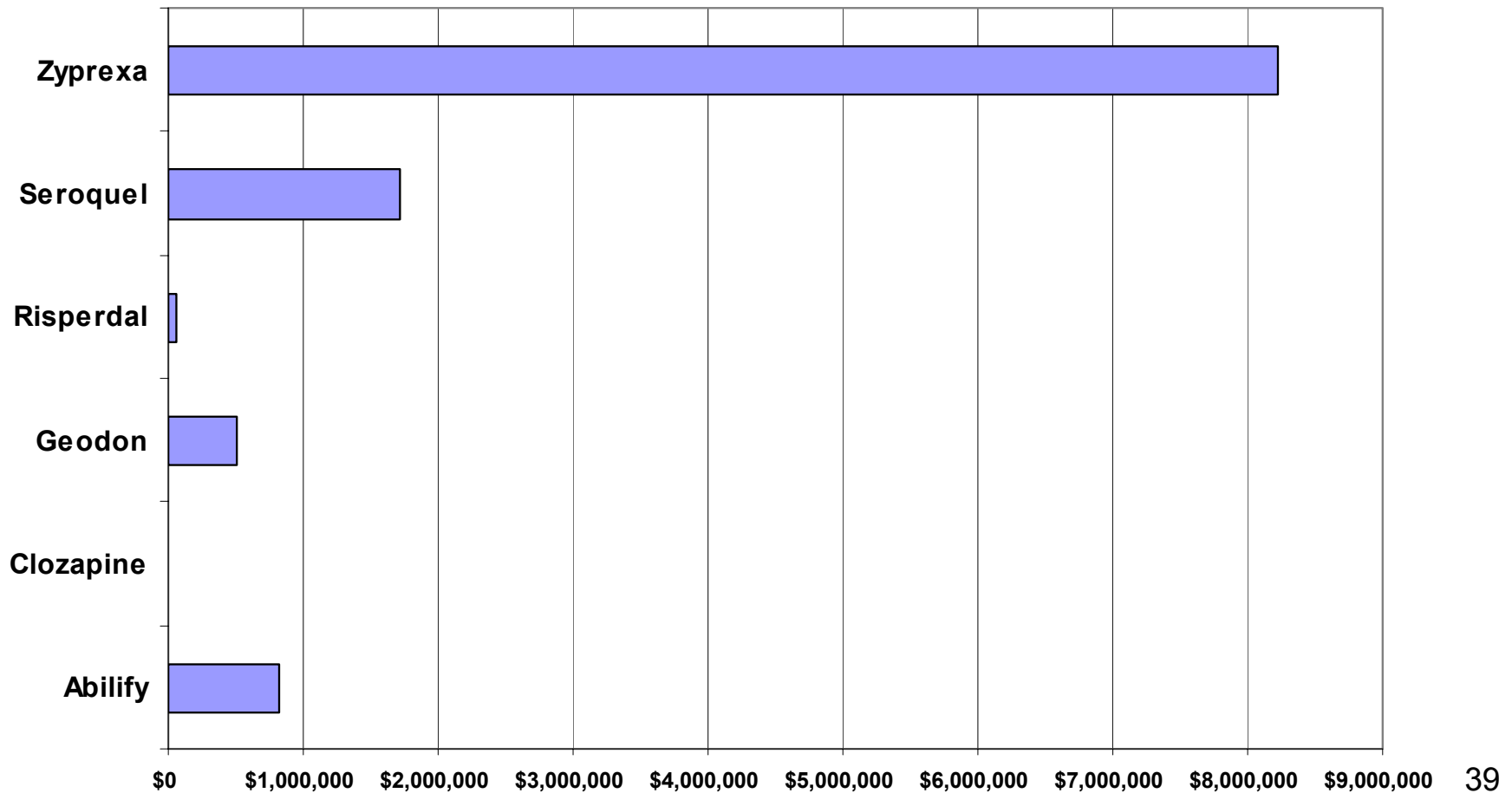
BRAND NAME	TOTAL NET
ZYPREXA	\$ 32,670,545.11
LIPITOR	\$ 24,868,811.97
RISPERDAL	\$ 22,132,813.86
SEROQUEL	\$ 18,863,357.04
NEURONTIN	\$ 17,755,337.32
ZOLOFT	\$ 13,850,442.16
SINGULAIR	\$ 12,792,489.81
PLAVIX	\$ 11,846,394.39
ADVAIR DISKUS	\$ 11,046,251.04
TOPAMAX	\$ 10,193,173.80
TOTAL	\$ 176,019,616.50

*** Atypical Antipsychotics represent 41.85% of total dollars for the top 10 brands

Atypical Antipsychotic Utilization Maximum Dosage Information

Kentucky Medicaid
SFY 2004

Annual Cost for Perscriptions Above Maximum Dosage= \$11,330,465



Roadmap to Quality

- Assist to develop protocol to move patients to compliance with FDA/Medicaid Guidelines